

GW/TMH:gh 12/19/05 464062.doc E-256-1999/0-US-06  
PATENT

Attorney Reference Number 4239-64087-01  
Application Number 10/070,853

purpose of examination if 1) there is no shared special technical feature, and 2) there would be an undue burden on the Examiner to examine the claims in a single application.

In the present case, neither of these conditions is met. It is alleged in the Office action that the special technical feature linking the embodiments of the invention is "the binding complex formed between adrenomedullin (AM) and AM binding peptides like factor H." This is a mischaracterization of the claims. Each of the claims refers specifically and explicitly to binding between adrenomedullin and all or part of human complement factor H.

Based on the overbroad characterization of the special technical feature, the Office action references Martinez *et al.* (*Endocrinology* 138:5597-5604, 1997). No specific allegation is made to indicate that Martinez *et al.* anticipates, renders obvious or otherwise abrogates the special technical feature to which the claims relate. Furthermore, the Office action provides no indication whatsoever of what aspect of the disclosure of Martinez *et al.* is deemed to relate to binding between adrenomedullin and human complement factor H or any subfragment thereof. In fact, the cited reference makes no mention of any protein capable of binding to adrenomedullin other than the cellular adrenomedullin receptor. The adrenomedullin receptor described in Martinez *et al.* is a specific seven-transmembrane G protein-associated receptor, which is wholly distinct and unrelated to the serum protein complement factor H. Nothing in the structure or function of the adrenomedullin receptor as described in the cited reference would have led a person of skill in the art to expect that complement factor H would bind to adrenomedullin, or that such a binding relationship would be relevant to diagnostic or other methods. Thus, Martinez *et al.* cannot anticipate or render obvious the special technical feature that links together claims 1-52 of the subject application, and the Restriction Requirement should be withdrawn.

Additionally, restriction of the invention into multiple groups is only appropriate if examination of the claims in a single application would pose an undue burden on the Examiner. In the present case, there is no undue burden, in particular because the claims share a special technical feature which links the methods and kits for performing such methods.

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Applicants further draw the Examiner's attention to the International Preliminary Examination Report (IPER) issued in the corresponding PCT application (a copy of which was filed with the instant application, on March 8, 2002). The IPER reports no lack of Unity of Invention under the same criteria applicable in this National Phase Application (PCT Rule 13.1). The IPER identifies Martinez *et al.* as a document defining the general state of the art, which is not considered to be of particular relevance. Indeed, the IPER specifically states that "[n]one of the available prior art documents discloses or refers to a complex comprising AM and the *newly identified* AM binding protein, human complement factor H" (paragraph 3.2, emphasis added).

Applicants fully appreciate that the U.S. Patent and Trademark Office is an independent searching authority in the context of the subject application, and is not necessarily bound by the interpretation of the prior art expounded in the IPER. Nonetheless, the current Office action provides absolutely no support for the contention that Martinez *et al.* abrogates the inventive contribution of the special technical feature that links the claims in the subject application, nor has any basis been provided for rejecting the interpretation of the IPER. Accordingly, sufficient grounds for restricting the claims in the subject application have not been established, and the Restriction Requirement should be withdrawn.

### Conclusion

It is believed that this case is in condition for substantive examination, and such action is requested. If anything further is required, or if the Examiner believes that a telephone conference would expedite consideration of this case, she is invited to telephone the undersigned.

Respectfully submitted,

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